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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,401	01/15/2004	G. Mike Makrigiorgos	700157-53471	6102

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EXAMINER	
BAUGHMAN, MOLLY E	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,401	MAKRIGIORGOS, G. MIKE	
	Examiner	Art Unit	
	Molly E. Baughman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/15/2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, and 3-5, drawn to a method of converting a double stranded nucleic acid into a hairpin structure, classified in class 435, subclass 91.2.

II. Claims 2, and 6-17, drawn to a method of amplifying a nucleic acid sequence of interest, classified in class 435, subclass 91.2.

III. Claim 18, drawn to a method of detecting DNA damage in a nucleic acid sequence of interest, classified in class 435, subclass 91.2.

IV. Claim 19, drawn to a method of converting a double stranded nucleic acid into a hairpin structure, classified in class 435, subclass 91.2.

V. Claims 20-29, drawn to a method of amplifying a nucleic acid sequence of interest, classified in class 435, subclass 91.2.

VI. Claims 30-34, drawn to a nucleic acid for amplifying a double stranded nucleic acid sequence of interest, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III, IV and V are directed to related methods of generating a PCR-amplified product which is substantially free of polymerase-induced errors. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the

inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions I, II, III, IV and V are drawn to different methods.

a) Invention I is drawn to a method of converting a double stranded nucleic acid into a hairpin structure, wherein a first single stranded nucleic acid is ligated to a first end of the upper strand of the template nucleic acid, and ligating a second single stranded nucleic acid which is non-complementary to the first single stranded nucleic acid to the first end of the lower strand of the nucleic acid (claim 1, part (1)). Inventions II, III, IV and V do not require this particular step in converting a sequence of interest into a hairpin structure.

b) Invention II is drawn to a method of amplifying the hairpin structure comprising a first primer that binds to at least a portion of the upper single stranded region, and a second primer that binds to at least a portion of the lower single stranded non-complementary region (claims 2, 6, and 14) and converting the PCR products into hairpin structures by a method which induces denaturation followed by sudden renaturation (claim 6, steps (b) and (c). These steps are not required by Inventions I, III, IV, or V.

c) Invention III is drawn to a method of amplifying a hairpin structure wherein a second primer binds to a second portion of the upper single stranded region and purifying the PCR products, wherein only those sequences of interest that contain damaged DNA are amplified (claim 18). Inventions I, II, IV, or V do not require this particular step as part of their methods. Furthermore, Invention IV does not require

amplification of the created hairpin structure, and Inventions II, and V are drawn to methods of removing damaged DNA (claims 6, 14, and 20).

d) Invention IV is drawn to methods of creating a hairpin structure comprising digesting the double stranded nucleic acid sequence with two restriction enzymes, which is not required by the method of Invention I, II, III, or V.

e) Invention V is drawn to a method of amplifying wherein a polymerase and primers are used to perform rolling circle amplification of the hairpin structure such that the upper and lower strand are continuously amplified and cleaving the amplification product with a restriction enzyme. These steps are not required by the methods of inventions I, II, III, or IV.

3. Inventions VI and (I, II, III, IV and V) are related as process of making, and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acid of Invention VI could be made by any of the methods of Inventions I, II, III, IV or V.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search and would be burdensome to search any combination of the inventions of Groups I, II, III, IV, or V together, (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is 571-272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Molly E Baughman
Examiner
Art Unit 1637 MEB 8/19/06

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
8/22/06